approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of monensin Type A medicated articles to make a revised formulation of a free-choice Type C medicated feed for pastured cattle for increased rate of weight gain.

EFFECTIVE DATE: March 26, 1997.

ADDRESSES: Data and information filed to support previous approvals may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Russell G. Arnold, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1674.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA 95–735, which provides for use of a monensin Type A medicated article to make a monensin Type C medicated feed/free-choice mineral granule containing 1,620 grams monensin per ton to be fed at 50 to 200 milligrams per head per day free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain.

Elanco Animal Health, Division of Eli Lilly and Co. filed a supplemental NADA that provides for a revised formulation of the Type C medicated feed/free-choice granule to properly reflect the salt and mineral content of the product. The supplemental NADA is approved as of March 26, 1997, and the regulations are amended in 21 CFR 558.355(f)(3)(x)(*b*) to reflect the approval.

In addition, § 558.355(f)(3)(x)(*b*) is amended in the table to correct some editorial and typographical errors in the entry for ''Ground limestone (33% calcium)'' and in the entries for ''6–01–080'' and ''4–04–152,'' respectively.

Approval of this supplement does not require a freedom of information summary because the approval concerns a change in salt and mineral content of the product. This change does not affect the product's safety or effectiveness. Therefore, no additional data was required for this approval. Data and information filed to support previous approvals may be seen in the Dockets Management Branch (HFA–305) (address above) between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in the table in paragraph (f)(3)(x)(*b*), in the first column, in the entry for ''Ground limestone (33% calcium)'' by adding the phrase ''or calcium carbonate (38% calcium)'' and in the third column in the first and third entries by removing the numbers ''6–01–080'' and ''4–04–152'' and adding in their place the numbers ''6–01–082'' and ''4–04–695'', respectively.

Dated: March 13, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–7551 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Change of Scientific Nomenclature

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of scientific nomenclature from *Corynebacterium* to *Actinomyces (Corynebacterium).* This change of nomenclature is necessary due to the scientific reclassification of the organism.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., 2001 West Main St., P.O. Box 708, Greenfield, IN 46140, has informed FDA that the scientific nomenclature for the bacterial organism *Corynebacterium pyogenes* has been changed to *Actinomyces (Corynebacterium) pyogenes.* This change of nomenclature is necessary due to scientific reclassification of the organism. The organism causes liver abscesses in cattle. Accordingly, the agency is amending the regulations in 21 CFR 558.355(f)(3)(ii)(*a*) and (f)(3)(ix)(*a*) and 558.625(f)(1)(i)(*b*) to reflect this change.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraphs (f)(3)(ii)(*a*) and (f)(3)(ix)(*a*) by removing the word ''*Corynebacterium*'' and adding in its place the words ''*Actinomyces* (*Corynebacterium*)''.

§ 558.625 [Amended]

3. Section 558.625 *Tylosin* is amended in paragraph (f)(1)(i)(*b*) by removing the word ''*Corynebacterius*'' and adding in its place the words ''*Actinomyces* (*Corynebacterium*)''.

Dated: March 13, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–7603 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

[MD–040–FOR]

Maryland Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.